

*B1
conced* 26 (amended). A skin-treatment method [comprising spraying on the skin a therapeutically or cosmetically effective amount of the composition] as claimed in claim [22] 23, wherein the hexamethyldisiloxane has a purity greater than 99.2%.

B2 Add the following claim.

28. The device as claimed in claim 10, wherein the composition comprises:

- 80 to 90% of hexamethyldisiloxane,
- 0.1 to 5% of the therapeutic agent or cosmetic substance,
- 1 to 10% of the thixotropic agent, and
- 0 to 20% of fillers or additives.

REMARKS

The present claims are 10-17 and 23-28.

Claim 10 is amended hereby in order to change the lower limit of the recited "thixotropic agent" to -- 1% --, instead of "0%," as described in the specification at page 6, lines 4-5. New claim 28 is supported by original claim 8 and page 6, lines 4-5 of the specification. Claims 23-26 are amended to recite the "compositions" represented by cancelled claims 18, 19, 21, and 22.

A new Abstract is submitted, herewith, as required in the outstanding Office Action.

In accordance with the present Amendment, the present claims now define a "device for spraying a composition onto the skin in the form of aerosol particles and a method of spraying a composition onto the skin. The present generic device claim (claim 10)

corresponds identically to previous claim 16, and the generic method claim (claim 23) corresponds identically to previous claim 25. That is, both the device and method claims include a composition containing three ingredients and an "optional" fourth ingredient. The three ingredients recited in the composition are "hexamethyldisiloxane", "a therapeutic agent or cosmetic substance", and a "thixotropic agent." The composition, *per se*, claims have been cancelled. Applicants respectfully submits that McCrea neither teaches nor suggests the presently claimed invention, for the following reasons.

McCrea teaches a composition for "topical delivery" to the skin, such as a topical cosmetic or a medicinal preparation (McCrea, column 1, lines 17-21). A particularly preferred use of the disclosed composition is as an antiperspirant (McCrea, column 7, lines 51-54). A critical and essential ingredient of the McCrea composition is a "suspending agent" that contains "a suspending wax composition" (McCrea, column 10, lines 41-43). The only means disclosed in McCrea for applying the composition to the skin is a "roll-on antiperspirant product" (McCrea working examples 1-8), a "semisolid sunscreen product" (McCrea working example 9).

As opposed to the presently claimed invention, McCrea does not teach or suggest that his composition can be applied by spraying onto the skin. More particularly, McCrea neither teaches nor suggests placing his composition into a device that can spray the composition onto the skin.

In order to demonstrate the obviousness of a claimed combination of limitations, the cited prior art must describe all of the limitations found in the claim and the obviousness of combining all of these limitations in the manner claimed. All "limitations of a claim must

be considered in determining the claimed subject matter as is referred to in 35 U.S.C. § 103 and it is error to ignore specific limitations distinguishing over the reference." *Ex parte Murphy*, 217 USPQ 479, 481 (POBD APP 1982). In the present situation, the prior art cited in the statement of rejection fails to describe, as recited in the present claims, a "container" cooperating with "a flow valve extending into said container, and a means of propulsion." Furthermore, the cited art neither teaches nor suggests the presently claimed invention, which combines the container/flow-valve/means-of-propulsion article in combination with a composition, to effect a "device" as presently claimed. Accordingly, no *prima facie* case of obviousness has been demonstrated.

Applicants observe that the statement of rejection contains an allegation that the presently claimed invention involves a "conventional delivery device," which, somehow, renders the claimed combination obvious. The present method claims are considered, according to the statement of rejection, "inherent" in McCrea. Applicants respectfully submits that these allegations are, just that; *allegations* which are not sufficient to establish obviousness.

First of all, whether or not the delivery system recited in the present claims (container/flow valve/means of propulsion) is taught in the prior art does not, by itself, render inserting the "composition" recited in the present claims inside of such a delivery system obvious. With all due respect, the rejection is based on speculation and hindsight reasoning. That is, there is no demonstration of record that one of ordinary skill in the art would have considered it obvious to effect such a combination. The fact that all elements of a claimed combination are known, separately, does not make the combination obvious.

Ex parte Clapp, 227 USPQ 972 (BPA&I 1985). "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, 23 USPQ 2d 1780, 1783-84 (Fed. Cir. 1992). "It is facts which must support the legal conclusion of obviousness." *Ex parte Crissy*, 201 USPQ 689, 695 (POBD APP 1976). "The burden of establishing a *prima facie* case of obviousness falls upon the examiner. Therefore, the evidence upon which the examiner relies must clearly indicate that a worker of routine skill in this art would view the claimed invention as being obvious." *Ex parte Wolters*, 214 USPQ 735 (PBA&I 1982). Where the facts supporting obviousness are not of record, the examiner cannot "resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis." *In re Warner*, 154 USPQ 173, 178 (CCPA 1967). Since there is no evidence or scientific reasoning, of record, supporting that it would have been obvious to combine the delivery system and composition in the manner recited in the present claims, the statement of rejection fails to make a *prima facie* case of obviousness. Since a *prima facie* case has not been established, the holding of obviousness "absent evidence to the contrary" made in the statement of rejection is improper. Applicants need not produce evidence of patentability where the examiner has failed to establish a *prima facie* case of obviousness.

As for the alleged argument for inherency set forth in the statement of rejection, Applicants respectfully submit that the examiner has failed to meet the requisite standard for establishing obviousness based on a theory of inherency. A "retrospective view of inherency is not a substitute for some teaching or suggestion which supports the selection

and use of the various elements in the particular claimed combination." *In re Newell*, 13 USPQ 2d 1248, 1250 (Fed. Cir. 1989). "In relying on a theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teaching of the applied prior art." *Ex parte Levy*, 17 USPQ 2d 1461, 1464 (BPA&I 1990), emphasis in original. Before "the burden shifts," the examiner has "the initial burden of establishing a *prima facie* basis for the alleged inherency." 17 USPQ 2d @ 1463-64. For the doctrine of inherency to apply it must be "*inevitable*" from the teachings of the prior art. *In re Wylding*, 190 USPQ 59, 62 (CCPA 1976), emphasis added. Applicants respectfully submits that the examiner has not shown that "spraying" the composition disclosed in McCrea is an "*inevitable*" result of McCrea's teaching. McCrea discloses that its composition can be used as a "roll-on" and "semisolid" product. Neither of these delivery methods suggests a method of "spraying," in the manner presently claimed. Failure to demonstrate a *prima facie* case based on inherency renders the rejection for obviousness improper. Furthermore, Applicants respectfully submit that the examiner has failed to consider the entirety of the teachings of McCrea. The McCrea composition must include a "suspending wax." There is no explanation of record as to whether one of ordinary skill in the art would have considered a suspending wax-containing composition suitable for use in a spraying device or a spraying method in accordance with the presently claimed invention. "It is impermissible within the framework of Section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary

skill in the art." *In re Hedges*, 228 USPQ 685, 687 (Fed. Cir. 1986). Since the presently claimed invention includes a "composition" that can be sprayed onto the skin, the skilled artisan would not only have considered the ingredients expressly recited in the present claims that are also found in McCrea, but also the other ingredients that are required in accordance with McCrea's teachings, such as the "suspending wax."

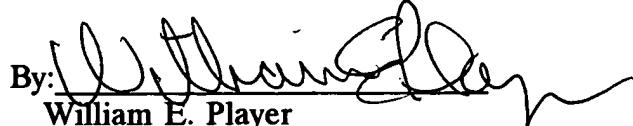
Finally, should the "suspending wax" of the McCrea composition render the composition unsuitable for spraying onto the skin, the present claims would, actually, exclude such an ingredient. By definition, the composition recited in the present claims must be suitable for spraying.

Applicants, also, submit that the mere presence in the McCrea composition of a disiloxane does not suggest the use of the composition for spraying. As discussed in the present specification, the presently claimed invention differs from known antiperspirant compositions that use a siloxane material in order to promote ease of spreading the material onto the skin (present specification, page 2, last complete paragraph.) McCrea expressly teaches that its composition is useful in a "roll-on antiperspirant product." This could have suggested to one of ordinary skill in the art that the siloxane material disclosed in McCrea was used in order to promote spreading of the material onto the skin. On the other hand, the presently claimed invention uses the hexamethyldisiloxane to promote transfer of the active substance found in the composition from inside the device to the skin during spraying. Although the presently claimed invention involves use of a siloxane, its use is, apparently, for a different purpose than disclosed in McCrea. Therefore, McCrea does not suggest the use of "spraying," or a device suitable for such a use.

Favorable action commensurate with the foregoing is requested.

Respectfully submitted,

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